K103277

Premarket Notification (510(k)) Summary

APR 19 2011

3M

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Suzanne Leung Regulatory Affairs
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Date of Summary: April 18, 2011

Device Name and Classification:

Common or Usual Name:	Sterilization Biological Indicator
Proprietary Name:	3M™ Attest™ 1491 Super Rapid Readout Biological Indicator 3M™ Attest™ 490 Auto-reader
Classification Name:	Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))

Predicate Devices:

- 3M™ Attest™ 1291 Rapid Readout Biological Indicator for Steam
- 3M™ Attest™ 290 Auto-reader

Description of Device:

The 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator (hereafter referred to as the 1491 BI) is a self-contained biological indicator designed to be used with the 3M™ Attest™ 490 Auto-reader (hereafter referred to as the 490 Auto-reader) to routinely challenge 270°F (132°C) and 275°F (135°C) gravity-displacement steam sterilization cycles having exposure times ≥ 3 minutes in length.

The 1491 BI is composed of a polycarbonate sleeve containing a spore carrier and media ampoule, enclosed with a blue cap. On each 1491 BI is a chemical process indicator that changes color from rose to brown when exposed to steam.

The 1491 BI is a further improvement over the current 3M Attest Rapid Readout technology. Both the Attest Rapid Readout BIs and the Attest Super Rapid Readout BIs utlize the α-glucosidase enzyme system, which is generated naturally within growing *G. stearothermophilus* spores. The α -glucosidase enzyme in its active state is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected in the 490 Auto-reader. The detection of fluorescence upon incubation of the 1491 BI in the 490 Auto-reader indicates steam sterilization failure.

The 490 Auto-reader is designed to incubate at 56°C and automatically read the 1491 BI for a fluorescent result within 30 minutes. The 490 Auto-reader is also designed to allow further incubation of the 1491 BI for an optional visual pH color change of the growth media at 24 hours. Both the fluorescent readout at 30 minutes and the optional visual color readout at 24 hours met the FDA's requirement of > 97% alignment with the result after the conventional incubation time of 7 days.

Indications for Use:

Use the 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator in conjunction with the 3M™ Attest™ 490 Auto-reader to monitor the cycles below.

Sterilization Type	Temperature	Time
Gravity Displacement Immediate Use Steam Sterilization Cycle (Flash)	270°F (132°C)	3 minutes
	270°F (132°C)	10 minutes
	275°F (135°C)	3 minutes
	275°F (135°C)	10 minutes

The 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator provides a final fluorescent result in 30 minutes. An optional visual pH color change result is observed in 24 hours.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Testing was conducted following the FDA guidance and standards below:

- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007
- ANSI/AAMI/ISO 11138-1:2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 1: General Requirements*
- ANSI/AAMI/ISO 11138-3: 2006/(R)2010 *Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes*
- ANSI/AAMI/ISO 18472:2006 *Sterilization of Health Care Product-Biological and Chemical Indicators: Test Equipment*
- United States Pharmacopeia, Chapter <1035> *Biological Indicators for Sterilization* and Chapter <55> *Biological Indicators – Resistance Performance Tests.*

Multiple lots of 3M™ Attest™ 1491 Super Rapid Readout Biological Indicators were evaluated for performance when used with the 3M™ Attest™ 490 Auto-reader. A Summary of the nonclinical testing is shown below.

Test	Acceptance Criteria	Result
Characterization of spores	> 90% Genetic similarity to *Geobacillus stearothermophilus* to ATCC™ 7953	Pass
D-Value	Greater than or equal to 10 seconds at 132°C Greater than or equal to 8 seconds at 135°C	Pass
Population (Total Viable Spore Count)	Greater than or equal to 10^6 spores	Pass
Survival/Kill Times	Survival Time = 1 min at 132°C or calculated survive time*, whichever is greater Survival Time = 40 seconds at 135°C or calculated survive time*, whichever is greater Kill time is calculated kill time* at 132°C and at 135°C *ANSI/AAMI/ISO 11138-1:2006, Annex E	Pass
Reduced Incubation Time	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout times: • Fluorescent result in 30 minutes • Optional visual color change result in 24 hours	Pass
Hold Time Assessment	D-value does not change when activated 7 days post-sterilization	Pass
Recovery Media Study	Ability to recover 10-100 organisms	Pass
Component Inhibition Studies	No impact of components on recovery of 10-100 organisms	Pass
Chemical Process Indicator	Chemical Process Indicator on the BI changes from rose to brown upon exposure to steam	Pass
Auto-reader Maintenance of Incubation Temperature	Must maintain 56+/- 2°C over a period of 24 hrs	Pass

The results of these evaluations showed that the new 3M™ Attest™ 1491 Rapid Readout Biological Indicator, when used with the 3M™ Attest™ 490 Auto-reader, complies with ANSI/AAMI/ISO 11138-1:2006/(R)2010 and ANSI/AAMI/ISO 11138-3:2006/(R)2010, the USP requirements for biological indicators, as well as the FDA's Guidance for Biological Indicators.

The 490 Auto-reader was tested for safety by Underwriters Laboratory to verify compliance to:

- *IEC 61010-1(2001) Second Edition; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements,*
- *IEC 61010-2-010 (2003) Second Edition: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials, and*
- *IEC 60825-1 (1993) First Edition with Am. 1(1997) and Am. 2 (2001); Standard for safety of laser products - Part 1: Equipment classification and requirements.*

In addition, the 490 Auto-reader has been tested by a certified Testing Laboratory to verify electromagnetic compatibility per:

- USA Title 47, Code of Federal Regulations (2009) for:
  - Radiated Emissions (FCC Part 15, Subpart B, Class A)
  - Conducted Emissions (FCC Part 15, Subpart B, Class A), and
- IEC 61326: *Electrical Equipment for Measurement, Control and Laboratory Use—EMC Requirements.*

Conclusion

The 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator and the 3M™ Attest™ 490 Auto-reader are substantially equivalent to the predicate devices, the 3M™ Attest™ 1291 Rapid Readout Biological Indicator for Steam, cleared under K900771, and 3M™ Attest™ 290 Auto-reader, cleared under K004009, in terms of their intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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APR 19 2011

Re: K103277
Trade/Device Name: 3M™ Attest™ 1491 Super Rapied Readout, Biological Indicator for Steam, 3M™ Attest 490 Auto-reader
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: March 14, 2011
Received: March 25, 2011

Dear Dr. Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Z

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103277

Device Name: 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator for Steam
3M™ Attest™ 490 Auto-reader

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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